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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,469	07/27/2001	Fabio Cinelli	CM-2017MC	1554

27752 7590 09/25/2002

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EXAMINER

WYROZEBSKI LEE, KATARZYNA I

ART UNIT	PAPER NUMBER
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1714

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,469

Applicant(s)

CINELLI ET AL.

Examiner

Katarzyna W. Lee

Art Unit

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 6 recites the limitation "C" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 or claim 1 does not specify what "C" is.

Claim Objections

3. Claim 1 is objected to because of the following informalities: Claim 1 in lines 2 and 4 recites an article comprising a wearing facing surface etc., where according to the specification "wearing" should read "wearer" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-11, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Dietz (WO 97/05171) or Dietz (US 5,670,557, US equivalent of WO patent).

The prior art of Dietz discloses composition for an adhesive, which can be utilized in a disposable article having adhesive for topical attachment to the skin, wherein the article further comprises a backing layer that can be porous or elastic, covering that is medical tape, wound dressing and the like (see claims of the prior art). The article also contains an adhesive layer, which at least partially covers the wearer's facing surface to afford topical attachment to the skin.

The composition of the adhesive of the prior art of Dietz is also described as one having both hydrophilic and hydrophobic continuous phases throughout.

The polymer utilized in the composition of the prior art of Dietz has both hydrophilic and hydrophobic monomers, which has peel strength when dry as well as when exposed to water.

The hydrophilic monomers as shown in the examples include N-vinyl pyrrolidone, acrylic monomers, acrylamide, sulfonic monomers and the like. Hydrophobic monomers include esters of acrylic acid such as isooctyl acrylate, butyl acrylate, methyl acrylate and combinations thereof.

In addition to the polymer having hydrophobic and hydrophilic monomers described above, the claims of the prior art of Dietz teach use of plasticizers.

With respect to the limitation of the ratios of wet peel strength and dry peel strength or as applicant refers to it as initial and final peel strength, the prior art of Dietz summarizes the peel test results in Table 6. Two tests are wet test and dry test, wherein the peel strength is usually, approximately in 1:1 ratio. Regardless if the adhesive is first peeled dry and then exposed to water or first wet peeled and then dried for the dry peel test, the results will be the same, because the peel strength of the adhesive composition is an inherent property arising from the components disclosed in the composition.

With respect to the actual value of the peel strength, the examiner noticed that the prior art of record discloses values in g/2.54 cm (or g/in) while the present invention reports the values in N/cm, but there is nothing that simple conversion of units would not fix. Knowing that: $1000 \text{ g} = 1 \text{ kg} = 9.8 \text{ N}$ and that $1 \text{ in} = 2.54 \text{ cm}$, the applicants values of 0.1 N/cm, 0.5 N/cm, 3.0 N/cm and 5.0 N/cm are equivalent to 0.0254 g/2.54cm, 127 g/2.54cm, 762 g/2.54cm and 11270 g/2.54cm respectively. Looking at the tables from the prior art of Dietz, the peel strength of the dry product lies in approximately 3.0 N/cm and slightly higher (50 g/cm range). Therefore, peel strength of the prior art lie within the peel strength limitations of the present invention. In addition, the claims of the prior art of Dietz teach peel adhesion of at least 3 N/100 mm, which is equivalent to 3 N/10 cm or 0.3 N/cm.

With respect to the properties of the modulus, the examiner also noticed that such are directly proportional to the thickness of the adhesive film. Since every adhesive layer has a thickness in range of mil-mm ($1 \text{ mil} = 0.0254 \text{ mm}$) and the same peel strength, then the adhesive

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of the prior art of Dietz will automatically inherently satisfy the requirements of 5-9 of the present invention.

Next issue to consider is the water absorption capacity of the adhesive composition. As it was mentioned earlier, the hydrophilic component of the prior art of Dietz comprises water-absorbing resins such as acrylates, their salts, N-vinyl pyrrolidone and the like. These polymers inherently absorb large amounts of water in as much as 10 times their own weight, which is evident from attached to this office action a printout from Aldrich catalog, where 1 gram of partial salt of acrylic acid will absorb as much as 45 g of 1% saline solution and which is way above 3 % limitation.

In addition the prior art of Dietz does not teach anywhere in the specification or claims to utilize hydrocolloid. Since the applicant does not disclose lower limitation of the amount of hydrocolloid, such can therefore be zero.

In the light of light above disclosure, the prior art of Dietz anticipates claims rejected above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz (WO 97/05171) or Dietz (US 5,670,577) in view of Bischof (WO 97/24149).

The discussion of the disclosure of the prior art of Dietz from paragraph 5 of this office action is incorporated here by reference.

The difference between the present invention and the disclosure of the prior art of Dietz is the recitation of the plasticizers of the present invention as well as recitation of hydrocolloids.

With respect to the above difference, the prior art of Bischof discloses composition for an adhesive for topical attachment to the skin. The adhesive comprises hydrophilic monomers, which overlap with those disclosed in the prior art of Dietz and those disclosed in the present invention.

In addition to the polymeric component, the specification of the prior art of Bischof and especially its examples disclose use of plasticizers. The plasticizers include polyethylene glycol, polyoxyethylene glycol, polyhydric alcohols, glycerol and the like. The plasticizing compounds of the prior art of Bischof overlap with those disclosed in the present invention. Plasticizers are utilized in the amount of up to 80 % by weight.

The prior art of Bischof also discloses use of particulate hydrocolloids, which are also aids in absorption of water. These hydrocolloids are utilized preferably in the amount of 1-8 % by weight (page 10).

Use of plasticizers as well as hydrocolloids in small amounts allows the adhesive composition to function as a humecant and allows the composition to retain sufficient amounts of water within the adhesive. The resulting adhesive has good peel properties.

In the light of the above disclosure, having two references at hand, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize the plasticizers and hydrocolloids of Bischof in the composition of Dietz and thereby obtain pressure sensitive adhesive. The combination is obvious, because both prior art references disclose pressure sensitive adhesive composition for topical attachment to the skin. In addition, it is well settled

that it is prima facie obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Linder* 457 F.2d 506,509, 173 USPQ 356, 359 (CCPA 1972). Also, the combination of two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to for a third composition that is to be used for the very same purpose may be prima facie obvious. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 426 (CCPA 1971).

10. Claims 5-15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz (WO 97/05171) or Dietz (US 5,670,577) in view of Corzani (EP 855,190).

The disclosure of the discussion of the prior art of Dietz from paragraph 5 of this office action is incorporated here by reference.

Following are the differences between the present invention and the prior art of Dietz: a) type of plasticizer, b) viscous and elastic modulus limitations, c) different type of the disposable article and its components, d) amount of wearer facing surface covered by the adhesive.

With respect to the difference c) the prior art of Corzani discloses disposable article such as sanitary napkin or panty-liner, wherein the article contains top sheet facing the person wearing the article, absorbent core and back sheet facing the undergarment. According to the specification no more than 20 % of the wearer facing surface is coated with the adhesive. The adhesive as disclosed in the prior art of Corzani is applied along peripheral edge of the absorbent article, which signifies that the adhesive is in continuous shape. The part of the article that does contain the adhesive, is preferably protected by release liner (page 7).

The composition of the prior art of Corzani according to the specification discloses polymers such as polyacrylics, polyethylene oxide, polyvinyl pyrrolidone, polyvinyl ethers and the like. The plasticizers of the prior art of Corzani include water, alcohols, glycols, polyglycols and the like. Additionally the prior art of Corzani teaches use of 0-5% use of gel stabilizing component.

The adhesive composition of the prior art of Corzani also satisfies the rheological properties of viscous modulus and elastic modulus, which ranges lie squarely in the middle of those of the present invention. Since the G' and G'' at 37°C satisfy the claims of the present invention such adhesive composition will obviously behave the same at a temperature of 25°C.

The composition of the prior art of Corzani is suitable as taught by the specification to form mixed phase hydrophobic and hydrophilic adhesive, which comprises polymer, plasticizer and tackifier. The above composition has certain rheological properties and is utilized on disposable article such as sanitary napkin as a topical attachment to the skin.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize the plasticizers of the prior art of Corzani in an adhesive Dietz, which then can be applied to sanitary napkin and thereby obtain the claimed invention. Such combination is obvious, since both prior art reference teach adhesive for topical attachment to the skin utilized with disposable articles. In addition, the prior art of Dietz teaches use of plasticizers.

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11. Claims 16, 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz (WO 97/05171) or Dietz (US 5,670,577) in view of Boundry (US 6,227,106 B1)

The discussion of the disclosure of the prior art of Dietz from paragraph 5 of this office action is incorporated here by reference.

The difference between the present invention and the prior art of Dietz is method of applying the adhesive to the article and the amount of the adhesive applied.

With respect to the above difference, the prior art of Boundry discloses disposable article, which has an adhesive having peel strength adequate for topical application of the article to the skin.

The adhesive of the prior art of Boundry can be applied to the skin slot coating technique (col. 13). The adhesive can be applied in various designs and it does not cover the entire surface of the article.

The prior art of Boundry teaches that the adhesive is applied in amount of 0.001-0.5 g/cm², which is equivalent to 1-50 g/m².

Although the range in which the adhesive of Boundry is applied is lower than that of the present invention, it would have been obvious to utilize such amount as well as the larger amount in the prior art of Dietz for the following reason: The adhesives of the prior art of Dietz and the present invention utilize compositions, which overlap and which are applied to disposable articles. In addition, both the prior art of Dietz and the present invention disclose adhesives having overlapping peel strength. This suggests, that the consistency of the adhesive of the present invention and the prior art of Dietz is very similar. In addition, both the prior art of Dietz

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and the present invention disclose an adhesive, which when applied has thickness on millimeter scale.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize the slot coating and amounts of the adhesive as discussed in the prior art of Boundry in the composition of Dietz and thereby obtain the claimed invention. Use of the slot coating and the amount of adhesives with the article of Dietz would also result in article having peel strength adequate to be used for topical attachment to the skin.

Priority

The applicant only provided copy of the document filed on 2/2/1999. The document filed in 2/2/2000 is missing and needs to be submitted. In addition, copies of the document received are photocopies and not certified.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katarzyna W. Lee whose telephone number is (703) 306-5875. The examiner can normally be reached on Mon-Thurs 6:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (703) 306-2777. The fax phone numbers for the

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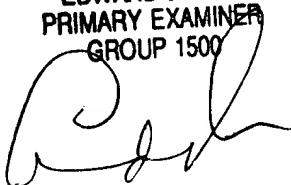
organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KIWL

September 12, 2002

EDWARD J. CAIN
PRIMARY EXAMINER
GROUP 1500

A handwritten signature in black ink, appearing to be "E. J. Cain", written over the printed name and title.

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